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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,986	10/17/2003	Nancy Jean Britten	PC27098	1367

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSKala@Pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/687,986	BRITTEN ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,15-21,23-28,30-40 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,15-21,23-28,30-40 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/09 has been entered.

Election/Restrictions

Applicant's election with traverse of group I (claims 1-40), election of ceftiofur hydrochloride as the antibacterial substance, election of Labrafil M-19944CS, which is a polyglycolized glyceride having oleic acid as the main fatty acid component, as the amphipathic oil, and cottonseed oil as the non-aqueous carrier in the reply filed on 2/28/08 is acknowledged. Applicants elect, with traverse, the mammary gland as the single organ. The traversal arguments have been addressed in an office action dated 4/21/08.

Applicant's amendment to claims in the response filed on 7/13/09 has been acknowledged.

Claims 1-4, 15-21, 23-28, 30-40 and 49 are pending.

Claims 5-14, 22, 29 and 41-48 have been canceled.

Claims 1-4, 15-21, 23-28, 30-40 and 49 are examined on the merit.

Any objections and/or rejections made in the previous office action dated 4/13/09 and not specifically discussed in its original or modified form here are considered withdrawn.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

Applicant's arguments, see page 6, filed 7/13/09, with respect to claims 1, 21-26 and 30-40 have been fully considered and are persuasive. The anticipation rejection of claims 1, 21-26 and 30-40 has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 15-21, 23-28, 30-40 and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,299,501 (Patil) in view of US 2002/0110561 A1 (Teagarden) as stated in the office action dated 10/28/08 and as reiterated below. The rejection has been modified to reflect amendments to claims. Response to applicant's arguments appears at the end of the reiterated rejection.

In the instant invention applicants claim a pharmaceutical composition 'consisting of' a **vehicle** comprising (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax, and (c) a pharmaceutically acceptable non-aqueous carrier, stably dispersed therein an antibacterial substance in an antibacterially effective amount wherein the antibacterial substance is cephalosporin.

Patil discloses semisolid dispersion of pharmaceutical composition comprising pharmaceutical materials (column 3, lines 7-9), pegicol-5-oleate (amphipathic oil of the instant invention), mineral oil (non-aqueous carrier of the instant claim), microcrystalline wax (in examples 3 and 4). This reads on instant claims 1, 21, 23-26 and 49. Since the instant claim 1 does not identify a specific antibacterial substance, the disclosure of active agent as pharmaceutical material reads on the limitation of instant claim 1. Patil further discloses sorbitan sesquioleate as an emulsifier (example 4) and hence reads on instant claim 39. Patil also discloses that the percentage of amphipathic oil, i.e., pegicol-5-oleate as 3% (in example 3) that is within the range recited in instant claims 30-32 and 49. Patil discloses that the percentage of microcrystalline wax to be 10% (in example 4) that is within the range recited in instant claims 33-35. Patil discloses that the percentage of non-aqueous carrier, i.e., mineral oil as 25% (in

example 4) that is within the range recited in instant claims 36-38. The disclosure of benzoic acid in example 3 reads on the instant claim 40 that recite benzoic acid.

Patil does not teach ceftiofur hydrochloride (elected species of antibiotic substance) and the elected species of non-aqueous carrier cotton seed oil.

Teagarden teaches the composition comprising crystalline ceftiofur free acid (CCFA) (claim 11) and composition comprises of cottonseed oil (claim 8) that reads on instant claims 19, 27 and 49. Teagarden also discloses mono-, di and tri-glycerides of fatty acid esters of oleic, linoleic, etc., the examples include non-oils such as polyethylene glycol (end of [0038] on page 3). This reads on the definition of instant claim 21 for the amphipathic oil and hence further reads on instant claims 23-26. Teagarden also discloses that the composition is used in a method of treating or preventing bacterial infection in mammals (claims 34-36). Teagarden further discloses that composition is suitable for parenteral subcutaneous and intra-mammary, intravenous administration and for topical applications ([0061]). Since the active ingredient is administered to mammary glands, it is obvious it is useful in treating mastitis, a bacterial infection. This reads on instant claims 2 and 3. Teagarden further discloses that the composition can be administered subcutaneously to ears ([0063]) and hence reads on instant claim 4. Teagarden also disclose a therapeutically effective dosage of the ceftiofur ([0066]) and compositions containing 100 mg/ml (example 4), 200 mg/ml (example 2) and 300 mg/ml (example 7) that are well within the limits recited in the instant claims 16-18.

It would have been obvious to one skilled in the art to combine the teachings of Patil and Teagarden to arrive at the instant invention for a pharmaceutical composition comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b)

microcrystalline wax, and (c) a pharmaceutically acceptable non-aqueous carrier; said vehicle having stably dispersed therein an antibacterial substance in an antibacterially effective amount. Because, Patil teaches the use of microcrystalline wax, amphipathic oil and non-aqueous carrier for the preparation of compositions comprising pharmaceutical materials and Teagarden teaches the composition comprising the active ingredient ceftiofur free acid and cottonseed oil as the non-aqueous carrier. One would have been motivated to do so given the fact that Teagarden used the composition to treat bacterial infection of mammary glands and ear infection. Teagarden also discloses the importance of modification to carrier vehicle to make the in vivo performance of the bioactive substance controlled and predictable (page 5, column 1, [0066]). There would have been reasonable expectation success to modify the composition of cited references given the fact that the Teagarden teaches to modify the composition for mode of application, particular sites (organs) and organism being treated ([0065]).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants reproduce the entire [0038] paragraph of Teagarden to argue that the issue presented in the rejection was whether or not the carrier described in Teagarden was a polyglycolized glycerides prepared by the alcoholosis reaction of natural triglycerides with PEG. Applicants' further point out that PEG is "non-oil" and there is nothing in Teagarden that suggest if PEG is included as a component of the carrier. Applicants also states that Patil relates to a water containing emulsion and provides no suggestion of a non-aqueous formulation.

Applicant's arguments filed 7/13/09 have been fully considered but they are not persuasive.

It should be noted that Teagarden was used in the rejection because, Teagarden teaches the elected species of the antibacterial substance ceftiofur hydrochloride and the elected species of non-aqueous carrier cottonseed oil. Since Teagarden also discloses the non-aqueous carries wherein the carrier includes mono-, di- and triglycerides of fatty acid esters of oleic and linoleic acids which also includes PEG esters. It is clearly stated in the rejection that it reads on the definition of the amphipathic oils recited in the instant claim 21. Applicant's comment seems to be restricted to the fact that PEG is a non-oil moiety instead of reading in the context that the fatty acid ester comprises PEG molecules. Moreover, applicant's argument that Patil does not provide any suggestion of a non-aqueous formulation is also not persuasive because, the instant claims are not drawn to non-aqueous formulation. The instant claim is drawn with the transition term "comprises" and hence does not preclude other ingredients being present in the composition. See MPEP Section 2111.02 that states "The transitional term "comprising", which

is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004)."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-4, 15-21, 23-28, 30-40 and 49 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 32, 34-36, 38-40, 49-66 of copending Application No. 10/795,191. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present invention is drawn to a pharmaceutical composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier, with an antibacterial agent. The claims of Application No. 10/795,191 are drawn to a pharmaceutical

composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier, with an antibacterial agent and a second agent selected from the group consisting of anti-inflammatory agents, analgesics and antipyretics. The claims of Application No. 10/795,191 are obvious over the present invention because the claims of the instant invention are drawn to active agents being an antibacterial agent and are drawn with the transitional phrase "comprising" that does not preclude other agents being present in the composition. Therefore, the claims of the present invention which can comprise an antibacterial agent an anti-inflammatory agents, analgesics or antipyretics and hence reads on the claims of the copending application 10,795,191.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have not presented any arguments to the 'Double Patenting' rejection.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 contains the trademark/trade names for amphipathic oil "Labrafil™ M1944CS. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the species of several ethoxylated fatty acids and, accordingly, the identification/description is indefinite.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Andrew D Kosar/
Primary Examiner, Art Unit 1654